DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 8, 2014

Covidien, LLC
Saket Bhatt
Regulatory Affairs Manager
2000 Commonwealth Ave., Suite 110
Auburndale, MA 02466

Re: K142198
Trade/Device Name: BNX Fine Needle Aspiration System
Regulation Number: 21 CFR§ 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: NEU, FCG
Dated: August 8, 2014
Received: August 11, 2014

Dear Saket Bhatt,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Food and Drug Administration

Indications for Use

Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
BNX Fine Needle Aspiration System

Indications for Use *(Describe)*
The BNX FNA System is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The needle is designed with a passive (i.e., automatic) safety shielding feature to aid in the prevention of needle stick injury. The 19Ga. and 22Ga. BNX Aspiration Needles are also intended to implant fiducial markers under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.0 510(k) SUMMARY

This 510(k) Summary for the BNX Fine Needle Aspiration System is being submitted in accordance with 21 CFR 807.92.

Submitter's Name and Address:	Covidien llc 2000 Commonwealth Ave. Suite 110 Auburndale, MA 02466-2008
Contact Person:	Saket Bhatt, Regulatory Affairs Manager 540 Oakmead Parkway Sunnyvale, CA 94085 Phone & Fax: 408-328-7357 Email: Saket.Bhatt@covidien.com
Date:	August 8, 2014
Name of Medical Device:	Device Regulation: 21 CFR 878.4300 and 21 CFR 876.1075, Class II Common/Usual Name: Implantable clip and Gastroenterology-urology biopsy instrument Product Code: NEU (Marker, Radiographic, Implantable) and FCG (Kit, Needle, Biopsy) Proprietary Name: BNX Fine Needle Aspiration System Classification Panel: Gastroenterology-Urology Devices Panel
Predicate Devices:	The subject device is substantially equivalent to the BNX Fine Needle Aspiration System (K133008, cleared November 20, 2013). The expanded indication for delivery of fiducial markers is substantially equivalent to the Wilson-Cook Medical EchoTip Ultra Fiducial Needle cleared under K111895 (cleared April 27, 2012).
Device Description:	The BNX Fine Needle Aspiration (FNA) System is a sterile, single patient use endoscopic ultrasound aspiration needle. The device consists of the Beacon ™ Endoscopic Ultrasound Delivery System and BNX ™ Fine Needle Aspiration Needle which are assembled before insertion through the accessory channel of an ultrasound endoscope. The device is offered with needle sizes of 19, 22 and 25 ga (however only the 19 and 22 gauge needles will be indicated for fiducial delivery). The BNX FNA System has an integrated needle protection shield that automatically engages over the distal end of the needle during removal to cover the needle sharp. In this manner, the needle tip is covered to help protect against inadvertent needle sticks.
Indication For Use:	The BNX FNA System is used to sample targeted sub-mucosal and extramural gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The needle is designed with a passive (i.e., automatic) safety

	shielding feature to aid in the prevention of needle stick injury. The 19Ga. and 22Ga. BNX Fine Needle Aspiration Needles are also intended to implant fiducial markers under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.
Technological Characteristics:	The proposed BNX FNA System's indications for use and technological characteristics are identical when compared with the predicate BNX FNA System cleared in K133008. With respect to fiducial delivery, the BNX FNA System indication for use statement proposed is identical to the predicate Wilson-Cook Medical EchoTip Ultra Fiducial Needle cleared under K111895. There have been no changes made to the design of the BNX FNA System to allow for expanded indication. The referenced BNX FNA device incorporates a long stiff metallic needle with stylet housed in a sheath with handle assembly. The handle is screwed onto the luer-lock connection of the endoscope. The needle is manipulated by a handle piston which is locked and unlocked by means of a screw to avoid advancement of the needle during introduction and withdrawal of the biopsy assembly. The tips of the Aspiration Needles are etched for enhanced ultrasonic needle visualization. The BNX FNA System is modular in design, i.e., the sheath and handle assembly are incorporated in a Delivery System as a separate component from the Aspiration Needle/stylet assembly. The modular design facilitates exchange of any size aspiration needle as the needle can be removed from the scope without requiring that the handle be disconnected. Additionally, the BNX FNA System has an integrated needle protection shield as a sharps injury protection feature that automatically engages over the distal end of the needle during removal to cover the needle sharp. In this manner, the needle tip is covered to help protect against inadvertent needle sticks. For delivery of fiducial markers the needle is loaded with the fiducial marker and fixated in place using bone wax. The fiducial marker is deployed into the target tissue by advancing the stylet.
Performance Data:	This premarket notification is supported with bench and simulated use testing. Testing performed demonstrates that the subject device is substantially equivalent to the predicate devices for the proposed intended use.
Conclusion:	Covidien has demonstrated that the proposed BNX FNA System is substantially equivalent to the predicate BNX FNA System and Wilson-Cook Medical EchoTip Ultra Fiducial Needle when used to implant fiducial markers under endoscopic ultrasound to radiographically mark soft tissue for future therapeutic procedures.